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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,741

Applicant(s)

KUDRNA ET AL.

Examiner

M. Thomas Andersen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 16, 20 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) received on 17 May 2004, is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97.

- 5 Accordingly, the information disclosure statement is being considered by the examiner.

Specification

- The disclosure is objected to because of the following informalities: page 2, line 5 should read "a particular user's desires" ; page 6, line 6 reads "tangs 72" and should likely read "tangs 77" ; page 6, line 7 reads "They 79 also" and should read "They also" ;
- 10 page 7, line 16 reads "a two downwardly" and should read "two downwardly" ; page 8, line 22 reads "to it 'piercing position'" and should read "to a 'piercing position'" ; page 9, line 26 reads "the external threats 166 mate" and should read "the external threads 166 mate" ; page 16, line 16 reads "60 is can be" and should read "60 can be" or "60 is" ;
- page 16, line 29 reads "has occurring" and should read "has occurred" ; page 17, line 7
- 15 reads "withdrawing" and should read "withdrawn."

Appropriate correction is required.

- The abstract of the disclosure is objected to because line 8 reads "in communications" and should read "in communication" ; line 10 reads "the magnetic forces from the magnetic affect the member, and releasing the one of" and should read
- 20 "the magnetic forces from the magnet affect the member, and releasing one of."

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- 5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims **1-7** are rejected under 35 U.S.C. 102(a) as being anticipated by **Freeman, U.S. 2003/0083686**. Freeman discloses a tissue penetration device that
10 uses magnetic forces. Figure 5 is a good representation of one of Freeman's embodiments termed "a cylindrical electric lancet driver" (paragraph 0031).

With regard to claim **1**, Freeman discloses a lancing method of driving an iron core 46 ("member") with magnetic forces produced by the coil pack 52 ("magnetic element"). The "member" 46 is in communication with the lancet 42, and the system is
15 used to pierce a user. (Freeman, paragraph 0138)

With regard to claim **2**, the coil patch is also used to "withdraw the driven lancet."
(Id.)

With regard to claim **3**, a tip of the lancet in Freeman exits the housing 40 to puncture the user. (Id.)

20 With regard to claim **4**, the lancet 42 is withdrawn back into the housing 40 by the magnetic element 52 and member 46. (Id.)

With regard to claim **5**, driving the lancet 42 involves the member 46 passing through the magnetic element or coil patch 52, as can be seen in figure 5.

With regard to claim 6, the lancet 42 is in communication with the member 46 and is driven by magnetic forces emanating from the coil patch 52. The magnetic forces attract and repel the lancet into and out of the housing 40 for the purpose of piercing a user. (Freeman, paragraph 0138)

5 With regard to claim 7, the lancet is also withdrawn back into the housing 40 by the magnetic forces. (Id.)

Applicant's claims 8-15, 18-19 read on Freeman's embodiment in figures 20-22. With regard to claim 8, the coils 214-217 are considered the "magnetic element" or, in the alternative, the permanent bar magnet 219 may be considered the "magnetic
10 element." Freeman also discloses that one or more of the coils 214-217 can be replaced with permanent magnets (paragraph 0174). Freeman's magnetic member 202 is considered the "member capable of being affected by magnetic forces." Both the magnetic element and member are within a "housing" 180 (or 188 and 191). Also, the device shown in figures 20-21 is to be placed in a larger housing shown in figures 52 or
15 53. The lancet 183 is in communication with the member 202 and is movable between a withdrawn position and a piercing position by movement of the member 202. The "armed position" is considered to be the position shown in figure 21 where the permanent bar magnet 219 is holding the member 202 in place prior to activation of the coils 214-217. Releasing the member from the armed position is accomplished by
20 activating the coils 214-217, and the magnetic forces created by current running through the coils 214-217 causes the member and lancet to move from a withdrawn position to the piercing position.

With regard to claim **9**, as mentioned above, the permanent bar magnet 219 effectively holds the member 202 in place, the lancet being in a withdrawn position.

With regard to claim **10**, adjusting the lancet for selectively controlling the positioning of the piercing position is discussed in paragraph 0194. Freeman discloses
5 either mechanically or electrically adjusting this parameter and others.

With regard to claim **11**, as can be seen in figure 21, the member 202 passes through the coils 214-217, i.e. one is permitted to pass through the other and the other to pass around the one.

With regard to claim **12**, the lancet is connected by means of the drive coupler
10 185 so that movement of the member 202 results in corresponding movement of the lancet. The drive coupler allows replacement of the lancet for future connecting.

With regard to claim **13**, the magnetic element 219 is oriented and configured so that in the armed position, the magnetic forces of the magnetic element 219 attract the member 202 to the magnetic element 219. The member 202 is released by drawing
15 current through the coils 214-217 and the member can be said to travel "towards" the magnetic element 219 and past the magnetic element 219 by the momentum of the traveling member created by the magnetic pull of the coils. This movement of the member results in the lancet traveling to the piercing position. Also, as discussed above, Freeman discloses the ability to interchange some of the coils 214-217 with
20 permanent magnets (paragraph 0174). These additional permanent magnets can be considered the "magnetic element." If some of the coils were replaced with permanent magnets, the additional permanent magnets in the coil housings 214-217 would also

hold the member 202 in a steady state position. Upon triggering the device and allowing current to run through the remaining coils, the member 202 would be attracted to the magnetic field created by the coils and the member would travel "towards" the "magnetic element" (the magnetic element consisting of the permanent bar magnet 219 and the permanent magnets used in place of the coils).

With regard to claim 14, the magnetic element 219 is oriented and configured to create a steady-state position that can be said to be between the withdrawn position and the piercing position. "Between" is defined as "In or through the position or interval separating" by The American Heritage® Dictionary of the English Language: Fourth Edition. The steady-state position can be said to be "between" the withdrawn position and the piercing position. Also, the magnetic forces of the magnetic member 219 hold the member 202 concentric therewith.

With regard to claim 15, the same process is described with regard to claim 13, except for the addition of "through the steady state position concentric with the magnet" and "back to the steady state position resulting in the lancet traveling to the piercing position and back to a position within the housing." The process described above with regard to claim 13 applies to the process in claim 15. The member 202 is released from the magnetic pull of the magnetic element 219 by creation of another magnetic pull by the coils, which creates momentum in the member 202. This momentum allows the member 202 to pass through the steady state position which it was in prior to activation of the coils 214-217. After the member moves towards the coils, the current in the coils

is reversed, and the member and lancet then travel back to a position within the housing (the housing for the lancet shown in figures 52 or 53).

With regard to claim 18, the disposable sampling module 410 in figure 51 is considered the end cap because along with the chamber 430 and socket 432, it houses the lancet 414. This "end cap," or disposable sampling module 410, is releasably connected to the socket 432 for disposal purposes.

With regard to claim 19: a switch is defined as "A device used to break or open an electric circuit or to divert current from one conductor to another" by The American Heritage® Dictionary of the English Language: Fourth Edition. In Freeman, a "switch" or sensor activates a driver which opens an electric circuit causing the finger to be lanced. Pressure is what activates the sensor in the same way that pressure activates a switch. This process is described in Freeman, paragraph 0019.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected because it recites the limitation "the outer shaft" in line 2.

There is insufficient antecedent basis for this limitation in the claim or in independent claim 8.

Claim 21 is rejected because it recites the limitation "the collar" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim **20** is objected to because of the following informalities: line 1 reads “engaging or disengaging a the member” and should read “engaging or disengaging the member.” Appropriate correction is required.

Allowable Subject Matter

5 Claims **16**, **20**, and **22** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

 With regard to claim **16**, the outer shaft moving relative to the inner shaft is interpreted as meaning that the inner shaft does not move, but the outer shaft does
10 move.

 With regard to claim **20**, engaging the member implies a mechanical engagement and not an electrical engagement. The examiner interprets disengaging the member as a mechanical disengagement performed by means of the switch in claim 19, and not a separate or additional switch.

15 With regard to claim **22**, if claim 21 is subsequently found allowable after properly claiming “the collar,” claim 22 will also be found allowable because it further restricts claim 21.

Conclusion

 The prior art made of record and not relied upon is considered pertinent to
20 applicant's disclosure. **Boecker**, Pub. No. US **2004/0098009** (disclosing a method and apparatus for body fluid sapling and analyte sensing; figure 98 is especially pertinent), **O'Brien**, US Patent No. **4,924,879** (disclosing a blood lancet device), **Harding**, US

Patent No. **5,613,978** (disclosing an adjustable tip for lancet device), **Verdonk**, U.S.

Patent No. **6,306,152** (disclosing a lancet device with skin movement control and ballistic preload), **Kheiri**, U.S. Patent No. **6,364,889** (disclosing an electronic lancing device), **Hamamoto**, U.S. Patent No. **6,730,046** (disclosing a body fluid sampling

5 device).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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M. Thomas Andersen

12 December 2005


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
12/27/05